

CLAIMS

*Sub D 1*

1. In a particulate drug delivery composition for intranasal delivery comprising a plurality of bioadhesive microspheres and a systemically active drug, the improvement comprising that at least 90 wt % of the microspheres of the composition have a diameter of between 0.1  $\mu\text{m}$  and 10  $\mu\text{m}$ .

5

2. A drug delivery composition according to Claim 1 wherein the microspheres are prepared from a material that will gel in contact with the mucosal surface.

10

3. A drug delivery composition according to Claim 1 or 2 wherein the microspheres comprise starch, starch derivatives, gelatin, albumin, collagen, dextran or dextran derivatives.

15

4. A drug delivery composition according to Claim 3 wherein the microspheres are starch microspheres.

5

5. A drug delivery composition according to Claim 1 wherein the microsphere material is cross-linked.

20

6. A drug delivery composition according to Claim 1 wherein the microspheres have been stabilised by heat treatment.

15

7. A drug delivery composition according to Claim 1 additionally comprising an absorption enhancer.

25

8. A drug delivery composition according to Claim 7 wherein the absorption enhancer is a surfactant, a lysophosphatidylecholine or a lysophosphatidylglycerol.

30

9. A drug delivery composition according to Claim 1 wherein the drug is a biologically active peptide.

10. A drug delivery composition according to Claim 9 wherein the peptide 5 is insulin or calcitonin.

11. A system for intranasal drug delivery comprising a drug delivery composition according to Claim 1 and a container having an orifice through which the composition can be delivered to the nasal mucosa in a gas stream.

10

12. A system according to Claim 11 wherein the system is such that, in use, the product of the flow rate and the square of the microsphere aerodynamic diameter is greater than  $2000 \mu\text{m}^2.\text{litres/min.}$

15 13. A method of delivering a drug to the nasal mucosa, comprising introducing a gas stream containing a composition according to Claim 1 into the nose.

20 14. A method of treating diabetes comprising introducing a gas stream containing a composition according to Claim 1 wherein the systemically active drug is insulin into the nose.

*plus  
g*

*add  
204*